	PTO-1: 01-2003		PATENT & TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER 125619					
		ANSMITTAL LETTER TO THE	U.S. APPLICATION NO. (If known, see 37 CFR 1.5)						
		ESIGNATED/ELECTED OF ONCERNING A FILING UN	10/553,211						
	RNAT	IONAL APPLICATION NO. 004/004506	PRIORITY DATE CLAIMED April 29, 2003						
	TITLE OF INVENTION ANTISOLVENT SOLIDIFICATION PROCESS								
Wrid	zer Ja	TS FOR DO/EO/US an Willem BAKKER; Robert Micha EN; Gerrald BARGEMAN; Cornel		erika REEDIJK; Jozef Johannes Maria E					
Appli	cant h	nerewith submits to the United State	s Designated/Elected Office (DO/E	O/US) the following items and other information:					
1.		This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.							
2.	\boxtimes	This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.							
3.		This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.							
4.		The US has been elected (Article 31).							
5.		A copy of the International Application as filed (35 U.S.C. 371(c)(2))							
		a. is attached hereto (required only if not communicated by the International Bureau).							
		b. has been communicated by the International Bureau.							
		c. is not required, as the application was filed in the United States Receiving Office (RO/US).							
6.		An English language translation of	the International Application as file	d (35 U.S.C. 371(c)(2))					
		a. is attached hereto.							
		b. has been previously submitted under 35 U.S.C. 154(d)(4).							
		c.							
7.		Amendments to the claims of the li	nternational Application under PCT	Article 19 (35 U.S.C. 371(c)(3))					
		a. are attached hereto (required only if not communicated by the International Bureau).							
		b. have been communicated by the International Bureau.							
		c. \square have not been made; however, the time limit for making such amendments has NOT expired.							
		d. have not been made and will not be made.							
8.		An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).							
9.		An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).							
10.		An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).							
Items	s 11 t	o 20 below concern document(s)	or information included:						
11.	\boxtimes	An Information Disclosure Statement under 37 CFR 1.97 and 1.98.							
12.	· 🗀	An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.							
13.		A preliminary amendment.							
14.		An Application Data Sheet under 37 CFR 1.76.							
15.		A substitute specification.							
16.		A power of attorney and/or change of address letter.							
17.		A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.							
18.		A second copy of the published international application under 35 U.S.C. 154(d)(4).							
19.		A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).							
20.		Other items or information:							

U.S. APPLICATION NO. (if known, s		INTERNATIONAL APPLICA PCT/EP2004/004506	TION NO.	ATTORNEY'S DOCKET NUMBER						
21. The following fees		PC1/EP2004/004506	 	125619 CALCULATIONS	PTO USE ONLY					
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BASIC NATIONAL FEE (37	\$									
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All situations not provided fo	or above		\$ 500.00							
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accompanied by an appropr	iate cover sheet (37	CFR 3.28, 3.31). \$40	.00 per property +	·						
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d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.										
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Customer Number: 25944 NAME: William P. Berridge REGISTRATION NUMBER: 30,024										
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Date <u>January 20, 2006</u>										
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PATENT APPLICATION

Group Art Unit: 1615 4161

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Wridzer Jan Willem BAKKER et al.

Application No.: 10/553,211

Filed: December 8, 2005 Docket No.: 125619

For: ANTISOLVENT SOLIDIFICATION PROCESS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR §1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

- \boxtimes This Information Disclosure Statement is being filed (a) within three months of 1. the U.S. filing date of this non-CPA application, OR (b) before the mailing date of a first Office Action on the merits in the present application. No certification or fee is required.
- \boxtimes 2. Relevance of references 12-13 and 55-62 is discussed in the present specification.
- 冈 3. References 1 and 11 were cited in the International Search Report. An English language version of the International Search Report is attached for the Examiner's information.
- 冈 In accordance with 37 CFR §1.98(a)(2)(ii), copies of any U.S. patents and patent 4. application publications are not attached.
- 冈 5. English language Abstracts of references 25, 27-29, 31-32, 34, 36-37, 39-41, 47-50, 52-54, 82, 86 and 92 are attached hereto.

Respectfully submitted

William P. Bernerge

Registration No. 30,02

WPB/nxy

Date: January 20, 2006

OLIFF & BERRIDGE, PLC P.O. Box 19928 Alexandria, Virginia 22320 Telephone: (703) 836-6400

DEPOSIT ACCOUNT USE AUTHORIZATION Please grant any extension necessary for entry; Charge any fee due to our

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Form PTO-1449 US Dept. of Commerce ATTY DOCKET NO. APPLICATION NO. PATENT & TRADEMARK OFFICE (REV. 8-83) 125619 10/553,211 INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) APPLICANTS Wridzer Jan Willem BAKKER et al. FILING DATE **GROUP** 4161 December 8, 2005 4645 U.S. PATENT DOCUMENTS **EXAMINER** SUB INITIAL DOCUMENT NUMBER DATE NAME **CLASS CLASS** /T.K./ 1. 6,221,398 04/24/2001 Edib JAKUPOVIC et al. /T.K./ 2. 5,269,926 12/14/1993 Elizabeth WEBSTER et al. /T.K./ 3. 5,278,106 01/11/1994 Tadao NAKASHIMA et al. /T.K./ 4. 6,514,958 02/04/2003 Pieter de HAAN et al. /T.K./ 5. 5,864,923 02/02/1999 Stephane Fabrice ROUANET et al. /T.K./ 2003/0176282 A1 6. 09/18/2003 Troy Ronald SEEHAFER et al. /T.K./ 7. 05/14/2002 6,387,399 Dennis R. MORRISON et al. /T.K./ 8. 5,876,480 03/02/1999 Michael MARKOWITZ et al. /T.K./ 9. 2002/0050659 A1 05/02/2002 William TOREKI et al. /T.K./ 10. 2002/0119916 A1 08/29/2002 EmadEldin M. HASSAN et al. FOREIGN PATENT DOCUMENTS SUB DOCUMENT NUMBER DATE COUNTRY **CLASS CLASS** /T.K./ 11. WO 03/032951 A1 04/24/2003 **WIPO** /T.K./ 12. WO 90/03782 A2 04/19/1990 **WIPO** /T.K./ 13. WO 00/38811 A1 07/06/2000 **WIPO** 14. EP 0 586 745 A1 03/16/1994 **EUROPEAN PATENT OFFICE** /T.K./ /T.K./ 15. WO 00/42078 A1 07/20/2000 **WIPO** /T.K./ 16. WO 99/05101 A1 02/04/1999 **WIPO** /T.K./ 17. WO 98/30650 A1 07/16/1998 **WIPO** 71.K./ 18. WO 98/18835 A1 05/07/1998 **WIPO** /T.K./ WO 97/49759 A1 19. 12/31/1997 WIPO /T.K./ 20. EP 0 492 712 A1 07/01/1992 **EUROPEAN PATENT OFFICE** OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.) DATE CONSIDERED 09/26/2008 **EXAMINER** /Tigabu Kassa/ Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in Examiner: conformance and not considered. Include copy of this form with next communication to applicant.

Sheet 1 of 7

Date: January 20, 2006

Sheet 2 of 7

Form PTO-1449 (REV. 8-83)	US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 125619			APPLICATION NO. 10/553,211			
INFOR	RMATION DISCLOSURE STATEMENT								
(Use several sheets if necessary)				APPLICANTS Wridzer Jan Willem BAKKER et al.					
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FOREIGN PATENT DOCUMENTS									
		DOCUMENT NUMBER		DATE	COUNTE	RY	CLASS	SUB CLASS	
/T.K./	21.	EP 0 672 351 A1	09/2	20/1995	EUROPEAN PATENT	OFFICE		-	
/T.K./	22.	WO 03/014196 A1	02/2	20/2003	WIPO				
/T.K./	23.	WO 98/47517 A1	10/2	29/1998	WIPO				
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/T.K./	26.	EP 0 452 140 A1	10/	16/1991	EUROPEAN PATENT	OFFICE			
/T.K./	27.	JP-A-04-100536 w/ abst.	04/	02/1992	JAPAN				
/T.K./	28.	JP-A-04-320643 w/ abst.	11/	11/1992	JAPAN				
/T.K./	29.	JP-A-05-184895 w/ abst.	07/	27/1993	JAPAN				
/T.K./	30.	EP 0 564 738 A1	10/	13/1993	EUROPEAN PATENT	OFFICE			
/T.K./	31.	JP-A-06-039259 w/ abst.	02/	15/1994	JAPAN				
/T.K./	K./ 32. WO 94/08626 A1 w/ abst. 04		04/	28/1994	WIPO				
/T.K./	33.	EP 0 685 167 A1	12/	06/1995	995 EUROPEAN PATENT OFFICE				
/T.K./	34.	EP 0 780 114 A1 w/ abst.	06/	25/1997	EUROPEAN PATENT	OFFICE			
/T.K./	35.	EP 0 121 265 A2	10/	10/1984	EUROPEAN PATENT	OFFICE			
/T.K./	36.	JP-A-02-006502 w/ abst.	01/	10/1990	JAPAN				
/T.K./	37.	JP-A-06-118636 w/ abst.	04/	28/1994	JAPAN				
/T.K./	38.	WO 97/36674 A1	10/	09/1997	WIPO	_			
/T.K./	39.	JP-A-04-258601 w/ abst.	09/	14/1992	JAPAN				
/T.K./	40.	JP-A-04-323224 w/ abst.	11/	12/1992	JAPAN				
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Sheet 3 of 7 Form PTO-1449 US Dept. of Commerce ATTY DOCKET NO. APPLICATION NO. (REV. 8-83) PATENT & TRADEMARK OFFICE 125619 10/553,211 INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) **APPLICANTS** Wridzer Jan Willem BAKKER et al. FILING DATE **GROUP** December 8, 2005 1615 U.S. PATENT DOCUMENTS **EXAMINER SUB** INITIAL DOCUMENT NUMBER DATE NAME **CLASS** CLASS FOREIGN PATENT DOCUMENTS SUB DOCUMENT NUMBER DATE **COUNTRY CLASS CLASS** /T.K./ 41. JP-A-05-064738 w/ abst. 03/19/1993 **JAPAN** ታጕቊ።06።001854 **ሃጵዮጵኒ** }P*************** ን3/26/1996 **ምምምየ** ⋠₽∞∧∞⊗₹∞∤∙≶₹₹₽⊗ 06/20/1999 *ኇ*፞ፇጚቔኯጚቔ ᢢᢪᢦᢊᢦ᠐ᡃᠮᢦᢓᢒᢒᢒᢒ 10/09/1999 **ን**የምምነፃ /T.K./ 46. EP 0 765 896 A1 04/02/1997 **EUROPEAN PATENT OFFICE** /T.K./ 47. JP-A-10-137577 w/ abst. 05/26/1998 **JAPAN** /T.K./ 48. JP-A-2000-053710 w/ abst. 02/22/2000 **JAPAN** /T.K./ 49. 08/25/1983 **GERMANY** DE 33 04 830 A1 w/ abst. /T.K./ 50. JP-A-02-265642 w/ abst. 10/30/1990 **JAPAN** /T.K./ 51. EP 0 433 094 A1 06/19/1991 **EUROPEAN PATENT OFFICE** /T.K./ 52. JP-A-05-184910 w/ abst. 07/27/1993 **JAPAN** /T.K./ JP-A-05-184911 w/ abst. 53. 07/27/1993 **JAPAN** /T.K./ 54. WIPO WO 02/02647 A1 w/ abst. 01/10/2002 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.) John TEXTER; "Organic Particle Precipitation"; Reactions and Synthesis in Surfactant Systems; 2001; pp. 577-607. /T.K./ /T.K./ M. NOCENT et al.; "Definition of a Solvent System for Spherical Crystallization of Salbutamol Sulfate by Quasi-Emulsion 56. Solvent Diffusion (QESD) Method"; Journal of Pharmaceutical Sciences; Vol. 90, No. 10; October 2001; pp. 1620-1627. 57. H. KROEBER et al.; "Micronization of Organic Materials by Crystallization with Compressed Gases"; 15th International /T.K./ Symposium on Industrial Crystallisation; Sorrento, Italy; September 2002.

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09/26/2008

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/Tigabu Kassa/

EXAMINER

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Sheet 4 of 7 Form PTO-1449 US Dept. of Commerce ATTY DOCKET NO. APPLICATION NO. (REV. 8-83) PATENT & TRADEMARK OFFICE 125619 10/553,211 INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) APPLICANTS Wridzer Jan Willem BAKKER et al. FILING DATE **GROUP** 4161 December 8, 2005 4646 U.S. PATENT DOCUMENTS **EXAMINER** SUB INITIAL **DOCUMENT NUMBER** DATE NAME **CLASS CLASS** FOREIGN PATENT DOCUMENTS SUB DOCUMENT NUMBER DATE **COUNTRY CLASS CLASS** OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.) /T.K./ 58. F. ESPITALIER et al.; "Crystallization of an Active Substance from Emulsion Droplets. Interactions Between Usage Properties and Process"; 12th Symposium on Industrial Crystallisation; Vol. 1; September 1993; pp. 25-31. 59. R. A. WILLIAMS et al.; "Controlled Production of Emulsions Using a Crossflow Membrane; Part II: Industrial Scale /T.K./ Manufacture"; Trans IChemE; Vol. 76; 1998; pp. 902-911. 60. Efrem CURCIO et al.; "Membrane Crystallizers"; Ind. Eng. Chem. Res.; Vol. 40; 2001; pp. 2679-2684. /T.K./ 61. Jia ZHIQIAN et al.; "Synthesis of nanosized BaSO₄ particles with a membrane reactor: effects of operating parameters on /T.K./ particles"; Journal of Membrane Science; Vol. 209; 2002; pp. 153-161. Jia ZHIQIAN et al.; "Synthesis of nanosized BaSO4 and CaCO3 particles with a membrane reactor: effects of additives on /T.K./ particles"; Journal of Colloid and Interface Sciences; Vol. 266; 2003; pp. 322-327. 63. J. W. MULLIN et al.; Crystallization; Third Edition; Butterworth-Heinemann, Ltd., Oxford; 1993. /T.K./ 64. Allan S. MYERSON; Handbook of Industrial Crystallization; Butterworth-Heinemann Series in Chemical Engineering, /T.K./ Boston: 1993. /T.K./ A. MERSMAN et al.; "Chapter 5: Crystallization"; Advances in Transport Processes VIII; 1992; pp. 287-318. T. G. ZIJLEMA et al.; "Antisolvent Crystallisation as an Alternative to Evaporative crystallization for the Production of /T.K./ Sodium Chloride"; World Salt Symposium, 8th; The Hague, Netherlands; May 7-11, 2000; pp. 495-500. 67. Hiroshi TAKIYAMA et al.; "Growth phenomena and morphology of NaCl crystals in drowning-out precipitation /T.K./ operation"; Advanced Purification in Crystallization Consortium; March 1996-March 1999; pp. 459-464 **EXAMINER** DATE CONSIDERED /Tigabu Kassa/

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Date: January 20, 2006

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Sheet 5 of 7 Form PTO-1449 ATTY DOCKET NO. US Dept. of Commerce APPLICATION NO. (REV. 8-83) PATENT & TRADEMARK OFFICE 125619 10/553,211 INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) APPLICANTS Wridzer Jan Willem BAKKER et al. FILING DATE **GROUP** 4161 December 8, 2005 lateratory. U.S. PATENT DOCUMENTS **EXAMINER** SUB INITIAL DOCUMENT NUMBER DATE NAME **CLASS CLASS** FOREIGN PATENT DOCUMENTS **SUB** DOCUMENT NUMBER DATE **COUNTRY CLASS CLASS** OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.) J. MYDLARZ et al.; "Crystallization and agglomeration kinetics during the batch drowning-out precipitation of potash 68. /T.K./ alum with aqueous acetone"; Powder Technology; Vol. 65; 1991; pp.187-194. Tjakko ZIJLEMA; "The Antisolvent Crystallisation of Sodium Chloride"; PhD Thesis; Delft University of 69. /T.K./ Technology; Delft University Press; October 19, 1999. 70. Harald OOSTERHOF; "Antisolvent crystallization of Sodium Carbonate"; PhD Thesis; Delft University of Technology, /T.K./ Universal Press Science Publishers, Veenendaal; December 13, 1999. 71. P. PUHLFÜRß et al.; "Microporous TiO₂ membranes with a cut off <500 Da"; Journal of Membrane Science; Vol. 174; /T.K./ 2000; pp. 123-133. 72. M. A. M. BEERLAGE; "Polyimide ultrafiltration membranes for non-aqueous systems"; PhD Thesis; Universiteit Twente; /T.K./ 1994. H. J. ZWIJNENBERG et al.; "Acetone-Stable Nanofiltration Membranes in Deacidifying Vegetable Oil"; J. Am. Oil. 73. /T.K./ Chem. Soc.; Vol. 76, No. 1; 1999; pp. 83-87. 74. D. BHANUSHALI et al.; "Performance of solvent-resistant membranes for non-aqueous systems: solvent permeation /T.K./ results and modeling"; Journal of Membrane Science; Vol. 189; 2001; pp. 1-21. 75. X. J. YANG et al.; "Experimental observations of nanofiltration with organic solvents"; Journal of Membrane Science; /T.K./ Vol. 190; 2001; pp. 45-55. 76. J. A. WHU et al.; "Nanofiltration studies of larger organic microsolutes in methanol solutions"; Journal of Membrane /T.K./ Science; Vol. 170; 2000; pp. 159-172. Toshinori TSURU et al.; "Nanofiltration in non-aqueous solutions by porous silica-zirconia membranes"; Journal of 77. /T.K./ Membrane Science; Vol. 185; 2001; pp. 253-261. **EXAMINER**

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Date: <u>January 20, 2006</u>

Form PTO-1449 ATTY DOCKET NO. US Dept. of Commerce APPLICATION NO. (REV. 8-83) PATENT & TRADEMARK OFFICE 125619 10/553,211 INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) APPLICANTS Wridzer Jan Willem BAKKER et al. FILING DATE **GROUP** December 8, 2005 **16015**000 4161 U.S. PATENT DOCUMENTS **EXAMINER** SUB INITIAL DOCUMENT NUMBER DATE NAME **CLASS** CLASS FOREIGN PATENT DOCUMENTS SUB **DOCUMENT NUMBER** DATE COUNTRY CLASS CLASS OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.) 88. Paul HOLISTER et al.; "Nanocrystalline Materials: Technology White Papers nr. 4"; Cientifica; October 2003. /T.K./ 89. T. RAAB et al.; "New Materials for High Pressure Osmosis Membranes"; Institute of Process Engineering; Johannes /T.K./ Kepler University; Linz, Austria. 90. Rasool DINARVAND et al.; "Gelatin Microspheres for the Controlled Release of All-trans-Retinoic Acid Topical /T.K./ Formulation and Drug Delivery Evaluation"; Iranian Journal of Pharmaceutical Research; 2003; pp. 47-50. 91. Majeti N. V. RAVI KUMAR et al.; "Pharmaceutical Polymeric Controlled Drug Delivery Systems"; Advances in Polymer /T.K./ Science; Vol. 160; 2002; pp. 49-117. 92. Hiroyuki KAGE et al.; "Complex Coacervation Microencapsulation of Mono-Dispersed Droplets Prepared by Membrane /T.K./ Emulsification"; Kagaku Kogaku Ronbunshu; Vol. 23, No. 5; 1997; pp. 652-658. (with abstract) 93. Curt THIES; "Microencapsulation"; Kirk-Othmer Encyclopedia of Chemical Technology, Online DOI; article online /T.K./ posting date: December 4, 2000. 94. Si-Shen FENG et al.; "Chemotherapeutic Engineering: Application and further development of chemical engineering /T.K./ principles for chemotherapy of cancer and other diseases"; Chemical Engineering Science; Vol. 58; 2003; pp. 4087-4114. 95. S. J. PENG et al.; "Controlled Production of Emulsions Using a Crossflow Membrane"; Trans IchemE; Vol. 76, Part A; /T.K./ November 1998; pp. 894-901. 96. Norihito DOKI et al.; "Production of Sodium Chloride Crystals of Uni-Modal Size Distribution by Batch Dilution /T.K./ Crystallization"; Journal of Chemical Engineering of Japan; Vol. 35, No. 11; 2003; pp. 1099-1104. /T.K./ 97. J. H. ter HORST et al.; "CRYSTALLIZATION/Additives: Molecular Design"; 2000; pp. 931-990. **EXAMINER** DATE CONSIDERED /Tigabu Kassa/ 09/26/2008 Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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